AD_____

Award Number: DAMD17-01-1-0674

TITLE: A Randomized Clinical Trial of Cognitive-Behavioral Treatment for PTSD in Women

PRINCIPAL INVESTIGATOR: Charles C. Engel, M.D.

CONTRACTING ORGANIZATION: The Henry M. Jackson Foundation
Rockville, Maryland 20852

REPORT DATE: October 2004

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

20050407 162

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	October 2004	Annual (17 Sep 2003 - 16 Sep 2004)

4. TITLE AND SUBTITLE
A Randomized Clinical Trial of Cognitive-Behavioral Treatment for PTSD in Women

5. FUNDING NUMBERS
DAMD17-01-1-0674

6. AUTHOR(S)
Charles C. Engel, M.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
The Henry M. Jackson Foundation
Rockville, Maryland 20852

E-Mail: Charles.engel@na.amedd.army.mil

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT (Maximum 200 Words)

This study is a randomized clinical trial comparing two types of individual psychotherapy for treating PTSD in 384 female veterans and active duty personnel at 11 sites. The treatments are a trauma-focused approach, Prolonged Exposure therapy, and an approach focused on current needs and problems, Present Centered Therapy. Each site will enroll 32 patients over the 24 months of active recruitment in the study. The hypothesis is that Prolonged Exposure therapy will be more effective than Present Centered Therapy for the treatment of PTSD in female veterans and active duty personnel. The study has entered the randomized phase. There are no conclusions to date.

14. SUBJECT TERMS
Post-traumatic stress disorder

15. NUMBER OF PAGES
8

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

Table of Contents

INTRODUCTION

The study is a randomized single-blind clinical trial comparing two types of individual psychotherapy for treating Post Traumatic Stress Disorder (PTSD) in women. This is a VA Cooperative Study. Walter Reed Army Medical Center is the only participating DoD site. Eleven VA sites around the country began with the study. One VA site, Bay Pines, Florida, withdrew in December 2003. The enrollment goal for each site is 32 patients over 24 months of active recruitment in the study. All research data are compiled and analyzed at the VA Cooperative Studies Program Coordinating Center in Palo Alto, CA and is not shared with the individual sites until completion of the study in 2005.

The objective of the study is to evaluate the efficacy of Prolonged Exposure (PE) therapy for treating PTSD and associated problems in active duty and veteran women. The hypothesis is that PE will be more effective then Present Centered Therapy (PCT) for treatment of PTSD in female veterans and active duty personnel. The primary outcome in this study is PTSD severity at the 3-month follow-up assessment as measured on the Clinician Administered PTSD Scale (CAPS).

The treatments are a trauma-focused approach, PE, and an approach focused on current needs and problems, PCT. Both treatment conditions consist of 10 weekly 90 minutes sessions. PE procedures include education about common reactions to trauma, breathing retraining, prolonged (repeated) exposure to trauma memories, repeated in vivo exposure to situations the patient is avoiding due to trauma-related fear, and discussion of thoughts and feelings related to exposure exercises. The goal of PE is to reduce the individual's emotional response to the traumatic event or feared stimuli through habituation. PCT is designed to provide emotional support for the trauma victim with emphasis on the individual's current life. The goal of treatment is to reduce distress and to increase a sense of mastery in day-to-day life.

The work will significantly expand knowledge about the treatment of PTSD in military women. The methodology for the study is summarized as follows: All participants, including self-referrals, will enter the study through referral by mental health clinicians. Following informed consent, participants will be screened for inclusion and exclusion criteria. If they meet these criteria and agree to participate, they will be randomly assigned to one of the two treatments, which will occur weekly for 10 weeks. Subjects will be assessed before treatment, immediately following treatment, and 3 and 6 months after the end of treatment.

BODY

A total of 250 participants have been randomized as of August 2004. See Graph 1 for a breakdown of enrollment by site. The mean age is 44.7 ± 9.4 with a range from 22 to 78 years. Fifty-six percent (56%) of the participants are Caucasian and 63% are college educated. Fifty percent (50%) are either divorced or separated. See Graphs 2, 3 and 4 for additional demographic information.

A total of 210 randomized participants began study treatment with 135 of them completing the 10 treatment sessions. Thirty-one (31) remain in actual treatment. Forty-four (44) participants voluntarily terminated treatment. One hundred and fifty-one (151) participants completed the first post-treatment assessment, 123 completed the 3-month follow-up assessment, and 97 completed the 6-month follow-up assessment. Information regarding the numbers of patients receiving either PE or PCT are kept by the VA CSPCC and not shared with the individual study sites in this double blind protocol.

The Walter Reed Army Medical Center (WRAMC) site has randomized 7 participants. Additionally, 8 women participated in the study as training cases for the WRAMC therapists. The average age of the WRAMC participants is 41 years with a range of 29 to 64 years of age. Six (6) women are Caucasian and six (6) are African American. Two (2) are Hispanic and one (1) is Native American. Six (6) are college graduates, six (6) have completed some college, two (2) have professional degrees, and one (1) completed high school. Seven (7) are single, four (4) are married, three (30 are divorced, and one (1) is separated.

One (1) WRAMC randomized participant has completed all follow-up assessments, one (1) has completed the initial post –treatment follow-up, and one (1) has completed the 3-month follow-up. One (1) participant completed the 10 treatment sessions but did not participate in follow-up assessments. One (1) participant voluntarily withdrew from treatment following session 5. One (1) randomized participant was unexpectedly deployed overseas prior to beginning any treatment sessions. One (1) participant remains in treatment.

There have been 18 Serious Adverse Events (SAE) among the 250 randomized participants during this study. Four (4) involved suicide attempts, ten (10) were psychiatric hospitalizations, one (1) was a hospitalization for diabetic ketoacidosis, and two (2) were deaths unrelated to the study (one of a drug interaction confirmed by autopsy and one is being investigated as a homicide).

Participants at the WRAMC site have not experienced an SAE. A randomized patient at the WRAMC site experienced an increase in her PTSD symptoms during her study treatment. This decompensation was reported to WRAMC DCI and the HSRRB and was not considered an SAE. Thus far, the independent Data Safety Monitoring Board has not noted any association between the study intervention and SAEs and the rate of SAEs is generally low.

KEY RESEARCH ACCOMPLISHMENTS

- 250 randomized participants, including 7 at the WRAMC site
- 64% of post-treatment assessments have been completed
- Representative patient populations with large African American population
- Baseline characteristics have good balance with respect to the 2 treatment conditions
- Few Serious Adverse Events
- Good data quality with more than 90% completion rate
- Reported patients' expectations and satisfaction are high

REPORTABLE OUTCOMES

This information is reported for the WRAMC site only.

Presentations:

Sheliga, Vivian; Engel, Charles; Gonzalez, Denise; Woodard, Pamela. Special Care for Special Women. A PTSD Treatment Trial For Women: Challenges and Lessons Learned. Sixth Annual Force Health Protection Conference, US Army Center for Health Promotion & Preventive Medicine, Albuquerque, New Mexico, August 2003.

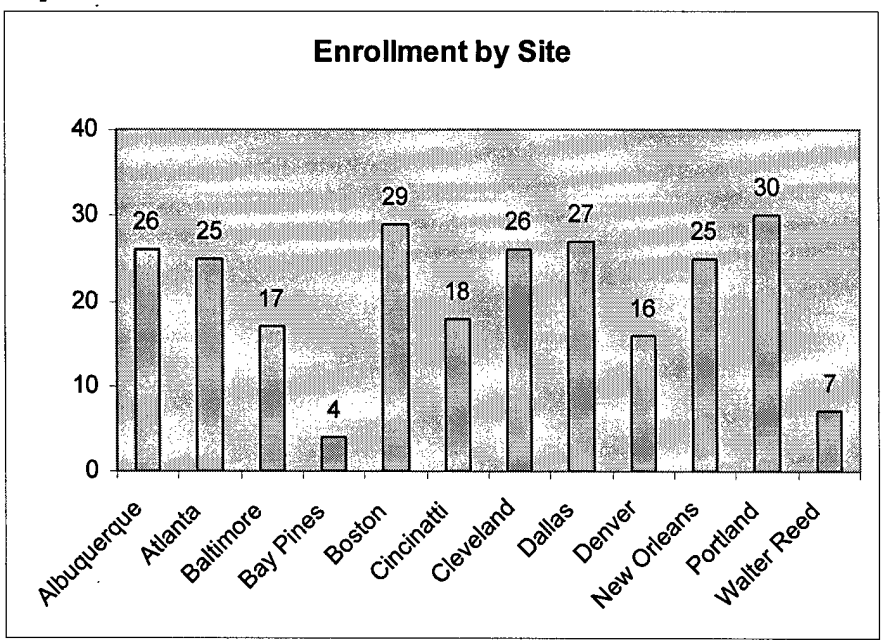
Gonzalez, Denise; Meyer, Nancy; Gore, Kristie; DeDeyn, Judy; Bruner, Victoria, Peterson, Catherine; Engel, Charles. The Care of Military Women with Traumatic Stress Concerns: What They've Said and What We've Learned. Seventh Annual Force Health Protection Conference, US Army Center for Health Promotion & Preventive Medicine. Albuquerque, New Mexico, August 2004.

Gonzalez, Denise; Meyer, Nancy; Gore, Kristie; DeDeyn, Judy; Bruner, Victoria; Peterson, Catherine; Engel, Charles. Post Traumatic Health Care Needs: What do Military Women Say?, International Society for Traumatic Stress Studies, Annual Conference, New Orleans, Louisiana, 2004.

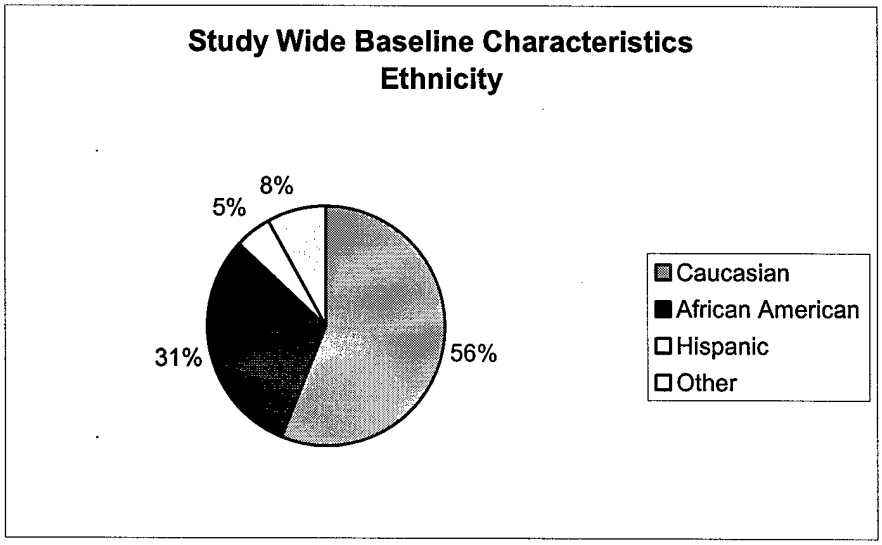
CONCLUSIONS

No conclusions are available at this time. The study continues at several sites through 2005. All data is compiled and analyzed at the VA Cooperative Studies Program Coordinating Center. Data analysis is not expected until 2006.

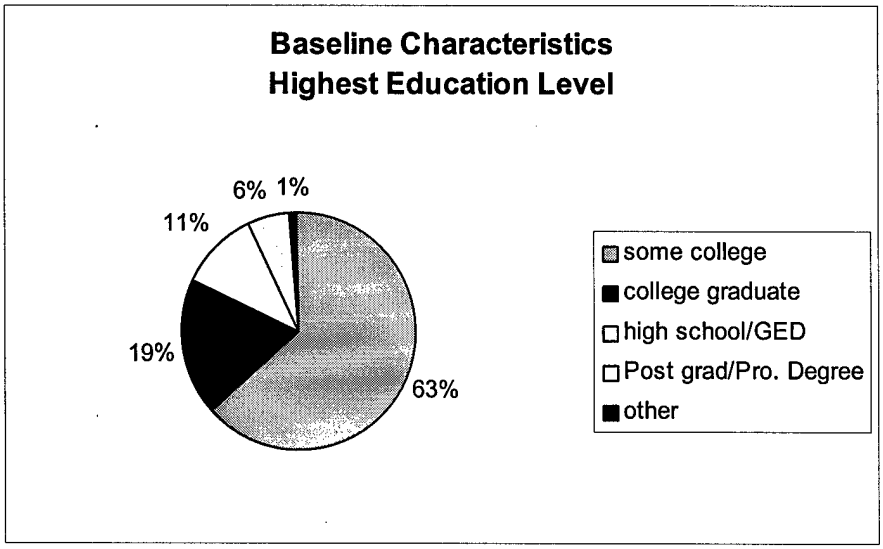
Graph 1



Graph 2



Graph 3



Graph 4